

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

IN RE NEW ENGLAND COMPOUNDING)	
PHARMACY, INC. PRODUCTS LIABILITY)	MDL No. 02419
LITIGATION)	Docket No. 1:13-md-2419-RWZ
)	
)	
This document relates to:)	
)	
Handy v. Box Hill Surgery Center, LLC, et al.)	
No. 1:14-cv-14019-RWZ)	
)	
Armetta v. Box Hill Surgery Center, LLC, et al.)	
No. 1:14-cv-14022-RWZ)	
)	
Torbeck v. Box Hill Surgery Center, LLC, et al.)	
No. 1:14-cv-14023-RWZ)	
)	
Kashi v. Box Hill Surgery Center, LLC, et al.)	
No. 1:14-cv-14026-RWZ)	
)	
Bowman v. Box Hill Surgery Center, LLC, et al.)	
No. 1:14-cv-14028-RWZ)	
)	
Dreisch v. Box Hill Surgery Center, LLC, et al.)	
No. 1:14-cv-14029-RWZ)	
)	
Davis v. Box Hill Surgery Center, LLC, et al.)	
No. 1:14-cv-14033-RWZ)	
)	
Farthing v. Box Hill Surgery Center, LLC, et al.)	
No. 1:14-cv-14036-RWZ)	

**BOX HILL DEFENDANTS’ CONSOLIDATED MEMORANDUM OF LAW
IN SUPPORT OF THEIR MOTION FOR PARTIAL SUMMARY JUDGMENT
CONCERNING PLAINTIFFS’ CLAIMS RELATING TO THE STANDARD OF CARE
AND PROFESSIONAL PRACTICE**

Defendants, Box Hill Surgery Center, L.L.C., Ritu T. Bhambhani, M.D., and Ritu T. Bhambhani, M.D., L.L.C. (hereinafter, collectively “Defendants,” “Box Hill Defendants,” or “Box Hill”), by undersigned counsel, submit this memorandum of law in support of their Motion For

Summary Judgment, pursuant to Rule 56 of the Federal Rules of Civil Procedure and the authority cited below.

I. INTRODUCTION

In each of the above captioned cases, Plaintiffs have generally asserted that the Box Hill Defendants failed to comply with the recognized standard of care and professional practice. The Box Hill Defendants now move for summary judgment on all claims related to the standard of care and professional practice because the undisputed facts establish that the Box Hill Defendants were compliant therewith at all relevant times.

The Court is well-versed on the background of these cases. Accordingly, the Defendants will refrain from restating all of the issues in these cases, which otherwise do not apply to the singular claim addressed in this motion for summary judgment.

This action is among hundreds, if not thousands, of lawsuits across the United States arising out of the administration of a steroid—preservative free methylprednisolone acetate (hereinafter “MPA”)—manufactured, contaminated, and distributed by New England Compounding Pharmacy, Inc. a/k/a New England Compounding Center (hereinafter “NECC”), a now dissolved corporation in Massachusetts. NECC provided MPA for purchase nationally to many physicians, ambulatory surgery centers, clinics, and hospitals, including Defendant Box Hill Surgery Center, which is an ambulatory surgery center solely owned by Defendant Bhambhani. It is alleged that as a result of negligent manufacturing, cleaning and sterilization practices by NECC, as well as improper testing and “clean-room” design, that certain vials or batches of MPA became contaminated with fungus in 2012 and may have caused varying levels of harm or injury to patients, who had received the MPA from their health care providers. It is alleged that the

contaminated vials were limited to certain lots: Lot # 05212012@68 (BUD 11/17/2012); Lot # 06292012@26 (BUD 12/26/2012); and Lot # 08102012@51 (BUD 2/6/2013).

The MPA in these lots was shipped to health care providers, including the Box Hill Defendants, who administered the drugs to patients before it was discovered that the lots were contaminated. These lots were recalled by NECC under pressure from the CDC on or about September 26, 2012, but not until after numerous patients fell ill, and some died, after developing fungal meningitis or other neurologic or infectious process.

As more fully set forth below, the Box Hill Defendants are entitled to summary judgment because they were compliant with the applicable standard of care and professional practice.

II. STATEMENT OF FACTS¹

1. The Plaintiffs' alleged injuries and causes of action arise from the fungal meningitis outbreak caused by contaminated, preservative-free, methylprednisolone acetate ("MPA") manufactured and sold by the New England Compounding Pharmacy, Inc., d/b/a New England Compounding Center ("NECC").²

2. The tainted vials were limited to certain lots: Lot # 05212012@68 (BUD 11/17/2012); Lot # 06292012@26 (BUD 12/26/2012); and Lot # 08102912@51 (BUD 2/6/2013).³

3. The Plaintiffs' claims against the Box Hill Defendants arise from alleged injuries suffered from potential exposure to MPA administered by Dr. Bhambhani and the Box Hill Defendants while performing epidural steroid injection procedures.⁴

¹ The actual exhibits referenced herein are all included with and following the Statement of Undisputed Material Facts.

² Dreisch Complaint at 3, ¶ 1.

³ Dreisch Complaint at 17, ¶ 51.

⁴ Dreisch Complaint at 37, ¶ 145.

4. Dr. Bhambhani and the Box Hill Defendants purchased preservative-free MPA from NECC because her previous employer used it, she had good results with it, and she was concerned about adverse events caused by preservatives.⁵

5. Similarly, thousands of health care providers across the country purchased drugs from the New England Compounding Center (“NECC”) even in just the five months preceding the meningitis outbreak at issue.⁶

6. NECC was regulated and inspected by the U.S. Food and Drug Administration (“FDA”).⁷ In a letter to Mr. Cadden and NECC dated December 4, 2006, the FDA affirmed its position that “the Federal Food, Drug, and Cosmetic Act (“FDCA”) establishe[d] agency jurisdiction over ‘new drugs,’ including compounded drugs.”⁸

7. In addition to such regulatory oversight, NECC also passed the inspection of the Massachusetts Board of Registration in Pharmacy about a year prior to the outbreak, and Brigham and Womens Hospital, a highly accredited and respected healthcare institution, as recently as a week prior to the time that the first batch of recalled MPA solution was manufactured in May 2012.⁹

8. After receiving orders from healthcare providers like Dr. Bhambhani, NECC failed to “follow either the proper USP 797 autoclaving sterilization procedure or its own standard operating procedure,” failed to take action on at least twenty-six occasions between January 2012 and September 2012 despite results from an internal environmental monitoring program that

⁵ See Deposition Transcript of Ritu T. Bhambhani, M.D., 71:25–73:16, excerpts attached as **Exhibit 1**.

⁶ See NECC Customer List Since 5/21/2012, attached as **Exhibit 2**.

⁷ See FDA Warning Letter, attached as **Exhibit 3**.

⁸ *Id.*

⁹ See Commonwealth of Massachusetts Inspection Report, attached as **Exhibit 4**; Brigham and Women’s Hospital Department of Pharmacy USP <797> Audit of NECC, attached as **Exhibit 5**; Brigham and Women’s Vendor Audit Survey Form, attached as **Exhibit 6**.

recorded bacteria and mold in the clean rooms used to produce “sterile” drug products, and distributed two lots of the recalled MPA before receiving results from sterility testing.¹⁰

9. The parties are in agreement that the applicable standard of care and professional practice did not require the Box Hill Defendants to travel to the NECC facility to perform an inspection prior to purchasing medications from NECC.¹¹

10. On March 22, 2017, Barry Cadden, the owner and head pharmacist of NECC, was convicted by a federal jury of racketeering, racketeering conspiracy, mail fraud and introduction of misbranded drugs into interstate commerce with the intent to defraud and mislead in connection with the 2012 nationwide fungal meningitis outbreak.¹² As a result of his criminal conduct, Mr. Cadden was subsequently sentenced to nine years in prison.¹³

11. In the summer and fall of 2012, NECC failed to fulfill its duty to accurately represent the safety and quality of its products to consumer and potential consumers and, in doing so, broke the law.¹⁴

12. NECC’s actions fell below the standard of care with regard to the contaminated lots of MPA.¹⁵

13. The Box Hill Defendants’ procurement of medications from NECC without using patient-specific prescriptions had no effect on whether the medications received were

¹⁰ Dreisch Complaint at 20, ¶ 66; *Id.* at 22, ¶ 81; *Id.* at 19, ¶ 64.

¹¹ See Deposition Transcript of Dr. Lloyd R. Saberski, 67:7–67:10, excerpts attached as **Exhibit 7**; see also Deposition Transcript of Dr. Laxmaiah Manchikanti, 104:10–105:6, excerpts attached as **Exhibit 8**.

¹² *Owner of New England Compounding Center Convicted of Racketeering Leading to Nationwide Fungal Meningitis Outbreak*, U.S. DEPT. OF JUSTICE (Mar. 22, 2017), <https://www.justice.gov/usao-ma/pr/owner-new-england-compounding-center-convicted-racketeering-leading-nationwide-fungal>.

¹³ Pharmacist in meningitis outbreak that kills dozens gets 9 years in prison, BOSTON GLOBE (June 26, 2017), <https://www.bostonglobe.com/metro/2017/06/26/feds-cadden-should-pay-for-fungal-meningitis-outbreak/kwet31ZTnsT4lpq4WRzkXO/story.html>.

¹⁴ See Deposition Transcript of Dr. Lloyd R. Saberski, 65:5–65:18, excerpts attached as **Exhibit 7**.

¹⁵ See Deposition Transcript of Dr. David Chason, 120:1–121:11, excerpts attached as **Exhibit 9**.

contaminated.¹⁶ Plainly stated, using patient-specific prescriptions would not have prevented Plaintiffs' injuries.¹⁷

14. The conduct of NECC, rather than the Box Hill Defendants, caused the MPA to be contaminated.¹⁸

15. NECC's actions were both the actual and proximate cause of the injuries suffered by Plaintiffs.¹⁹

III. STANDARD OF REVIEW

A moving party is entitled to summary judgment if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine dispute as to any material fact and that the moving party is entitled to judgment as a matter of law. FED. R. CIV. P. 56(c)(2). The moving party is "entitled to judgment as a matter of law" when it makes a sufficient showing on all essential elements of its case to which it has the burden of proof. *Celotex Corp. v. Catrett*, 477 U.S. 317, 317–18 (1986). If the non-moving party fails to make a sufficient showing on an essential element of his case, on which he would bear the burden of proof at trial, summary judgment is proper. *Id.* at 322.

A nonmoving party may avert summary judgment by showing that there exist specific facts that would present a genuine issue for trial. *Id.* at 324. To establish a genuine issue of fact sufficient to warrant trial, the nonmoving party "must do more than simply show that there is some metaphysical doubt as to the material facts." *Matsushita Elec. Indus. Co. Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986). The nonmoving party must set forth "specific facts showing there is a genuine issue for trial." *Anderson*, 477 U.S. at 248 (quoting FED. R. CIV. P. 56(c)(2)).

¹⁶ See Deposition Transcript of Dr. Lloyd R. Saberski, 167:13–168:16, excerpts attached as **Exhibit 7**.

¹⁷ See *id.*

¹⁸ See *id.*, 64:7–65:1, excerpts attached as **Exhibit 7**.

¹⁹ See Deposition Transcript of Dr. David Chason, 120:1–121:11, excerpts attached as **Exhibit 9**.

IV. LEGAL ARGUMENT

Under Maryland law, this Court must begin its analysis of a negligence action with the question of whether a legally cognizable duty exists. *Patton v. USA Rugby*, 381 Md. 627, 636, 851 A.2d 566, 571 (2004); *Remsburg v. Montgomery*, 376 Md. 568, 582, 831 A.2d 18, 26 (2003). The initial determination as to whether a duty exists is significant because "[t]here can be no negligence where there is no duty that is due." *Patton*, 381 Md. at 636, 851 A.2d at 570 (citing *W. Va. Central R. Co. v. State ex rel. Fuller*, 96 Md. 652, 666, 54 A. 669, 671-72 (1903)). The existence of a duty in a negligence action is a question of law to be decided by the court. *Dehn v. Edgecombe*, 384 Md. 606, 619-20, 865 A.2d 603, 611 (2005); *see also Patton*, 381 Md. at 636, 851 A.2d at 570. A duty, otherwise known as a standard of care when referring to medical negligence, is defined as what a reasonably prudent physician or health care provider would be required to do under same or similar circumstances in the care and treatment of a patient. *Board of Physicians v. Bernstein*, 894 A.2d 621, 645, 167 Md. App. 714 (2006).

In Count I of their respective Complaints, Plaintiffs set forth what appears to be a laundry list of "duties" that the Box Hill Defendants allegedly owed to them as a result of the physician-patient relationship. Under the guise of these "duties," it is essentially alleged that the Box Hill Defendants were required to inspect, investigate, and otherwise supervise NECC's compounding procedures, testing and safety policies, and its production facilities. Plaintiffs couch these "duties" as engaging in a "due diligence" of sorts prior to lawfully purchasing preservative-free MPA (hereinafter "MPA") from NECC. However, no such "due diligence" duty exist under Maryland law and the standard of care, as established by reasonable physicians similarly situated to Dr. Bhambhani, did not include such a requirement.

Plaintiffs not only fail to provide support for the contention that there is a "due diligence" duty, but they also fail to cite to any case law that held or found such a duty because no such case

law or support exists. In this instance, it is clear that it was the duty of the Massachusetts Board of Pharmacy,²⁰ not Dr. Bhambhani, a single Maryland physician, to regulate and license NECC and to ensure that NECC complied with Massachusetts pharmacy laws, established by the Massachusetts Board of Pharmacy. Even Plaintiffs' expert conceded that the standard of care did not require the Box Hill Defendants to travel to NECC's facility to perform an inspection prior to purchasing medications from NECC. *See* Deposition Transcript of Dr. Lloyd R. Saberski, 67:7–67:10, excerpts attached as **Exhibit 10**. Dr. Manchikanti, Box Hill Defendants' anesthesiology and pain management expert, also confirmed that there were no guidelines from any major medical associations requiring any performance of "due diligence" and that the Box Hill Defendants' actions were consistent with the practices of her reasonable peers. *See* Deposition Transcript of Dr. Laxmaiah Manchikanti, 104:10–105:6, excerpts attached as **Exhibit 11**. Dr. Manchikanti further explained that the Box Hill Defendants hadn't breached the standard of care in ordering medications from NECC given Dr. Bhambhani's previous experience and success using NECC products. *See id.*, 91:19–92:4, excerpts attached as **Exhibit 11**.

The parties to the instant matter are in agreement as to the elements and factors that determine the standard of care. Dr. Saberski, Plaintiffs' expert in internal medicine, anesthesiology, and pain management expert, testified in his deposition that aspects shaping the standard of care or practice in a particular field include formal education, training, information learned from mentors, discussions with other physicians, experience with patients, and just plain experience in one's practice. *See* Deposition Transcript of Dr. Lloyd R. Saberski, 50:14–51:13, excerpts attached as **Exhibit 10**. Dr. Saberski further testified that the standard of care is judged prospectively, rather than retrospectively in hindsight. *See id.*, 53:2–53:5, excerpts attached as

²⁰ The Massachusetts Board of Pharmacy is also known as the "Massachusetts Board of Registration in Pharmacy."

Exhibit 10. Ultimately, Dr. Saberski concluded that it would be fair to define the standard of care as what doctors in a similar situation would reasonably actually do. *See id.*, 50:8–50:11, excerpts attached as **Exhibit 10**.

It is undisputed that the actions of the Box Hill Defendants were on par with thousands of other physicians, clinics, and hospitals across the country in the same circumstances. Hundreds of those health care providers have been singled out and are now part of this MDL along with the Box Hill Defendants. Maryland law does not impose a duty on physicians or medical clinics to regulate the pharmacies from which they lawfully purchase medications, nor does Maryland law impose a duty on physicians to visit and/or evaluate a licensed pharmacy’s compounding facility prior to purchasing medications as Plaintiffs have shockingly alleged.

The Box Hill Defendants’ compliance with the applicable standard of care—which has been described by Plaintiffs’ experts as what doctors in a similar situation would reasonably actually do, *supra*—is further corroborated by the testimony of physicians similarly situated to Dr. Bhambhani in response to depositions by written question taken by the Box Hill Defendants. Deposition questions pertinent to the claim that the Box Hill Defendants breached the standard of care include the following:

10. Prior to purchasing medications from NECC, did a representative of [deponent] perform an in-person inspection of NECC’s compounding facility?

11. Prior to purchasing medications from NECC, did [deponent] conduct research into whether NECC had recalled any medications made by NECC?

12. Prior to purchasing medications from NECC, did [deponent] conduct any research into whether NECC had ever been named as a defendant in a products liability lawsuit?

...

14. Prior to purchasing medications from NECC, did [deponent] submit a Freedom of Information Act request to the FDA for documentation of disciplinary actions and/or warnings issues to NECC by the FDA?

...

17. At the time of [deponent's] purchases from NECC, did [deponent] have a policy and/or procedure in place prohibiting purchases from compounding pharmacies?

See, e.g., Notice of 30(B)(6) Deposition by Written Questions, pp. 2–3, excerpts attached as **Exhibit 12**. The Box Hill Defendants received answers from six healthcare institutions that span a significant region of the country. Specifically, responses were received from Premier Orthopedics & Sports Medicine (Hermitage, TN), Erlanger Health System (Chattanooga, TN), James E. Davis Ambulatory Surgical Center (Durham, NC), Montclair Orthopaedics Group (Glen Ridge, NJ), Cumberland Valley Surgical Center (Hagerstown, MD), and Peninsula Orthopaedic Associates, P.A. (Salisbury, MD). Not one institution was able to answer the aforementioned questions in the affirmative. *See, e.g.,* Deposition by Written Question of Cumberland Valley Surgical Center, 8:5–12:3, excerpts attached as **Exhibit 13**.

Apart from misrepresenting the recognizable duties imposed on the Box Hill Defendants as health care providers, Plaintiffs fail to allege that Dr. Bhambhani breached a recognizable duty or standard of care that actually does exist—namely, how other reasonably prudent health care providers would act under same or similar circumstances in treating their patients. Dr. Bhambhani, like thousands of other physicians with her credentials, administers epidural steroid injections to treat her patients' pain. Such treatment is wide-spread and accepted in the medical community for patients who suffer from back and neck pain. That is uncontroverted. Plaintiffs, however, fail to allege that Dr. Bhambhani, for example, used a negligent technique or otherwise breached accepted standards of care as it pertains to the actual treatment that she provided to the underlying patients in these actions.

Although the PSC has disclosed witnesses stating that the Box Hill Defendants deviated from the requisite standard of care, the witnesses' opinions are irreconcilable with the conduct of a substantial number of providers both in their very own communities and nationally. A witness offering the opinion that the norm is an aberration is completely unreliable, and falls short of the foundational requirements for expert testimony set forth in Federal Rules of Evidence and *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (2003).

Consistent with the practices of her reasonable peers, Dr. Bhambhani and other physicians (and the Box Hill Defendants) do not have a duty to regulate pharmacies or to engage in any type of special due diligence inspection or investigation prior to lawfully purchasing medications from a licensed pharmacy, such as NECC. Maryland law has never recognized any such duties with respect to physicians and/or clinics and the imposition of the same would mark a drastic expansion of existing law, and one better left to the legislature and policy makers, not the courts. Similarly, Plaintiffs have also failed to establish that the Box Hill Defendants deviated from the practices of reasonable, similarly situated physicians at the time of the alleged negligence.

Accordingly, the Box Hill Defendants are entitled to summary judgment as a matter of law because Plaintiffs are unable to establish that the Box Hill Defendants have breached any governing standard of care or professional practice.

V. CONCLUSION

For the foregoing reasons, the Box Hill Defendants respectfully request that the Court grant its motion for summary judgment.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this 18th day of September 2017, I served the above Memorandum upon the Clerk of the Court, using the CM/ECF system, which then sent a notification of such filing (NEF) to all counsel of record.

/s/ Gregory K. Kirby

Gregory K. Kirby, Esq.